MAY - 2 2012

510(k) Summary for the Posey Bed 8040 and Posey Bed 8060

SUBMITTER:

J. T. Posey Company
5635 Peck Road
Arcadia, California 91006 USA

CONTACT PERSON:

Bonnie Bishop, RAC
Vice President, Quality Assurance and Regulatory Affairs
Phone: (626) 454- 2195 (direct)
(626) 443-3143, extension 195
Fax: (626) 443-5012
E-mail: BBishop@posey.com

DATE PREPARED: April 24, 2012

DEVICE TRADE NAME: Posey Bed 8040 and Posey Bed 8060

COMMON/USUAL NAME: Enclosed bed canopy system used as passive restraint

CLASSIFICATION NAME: Protective Restraint (21 CFR §880.6760[20]), Code OYS

SUBSTANTIAL EQUIVALENCE: The proposed device when used with a compatible commercially available hospital bed is substantially equivalent to the Posey Bed 8070 as described in K103817 previously cleared by the FDA via the 510(k) notification process. The proposed device is also substantially equivalent to the Soma Safe Enclosure, cleared under K963701.

DEVICE DESCRIPTION: The Posey Bed 8040 and Posey Bed 8060 (Posey Bed 8040/8060) is an enclosed bed canopy system with an adjustable enclosed mattress compartment. The Posey Bed 8040 features a 73 cubic-foot, A-Frame, green nylon canopy with one zippered access panel and one drainage port opening. The Posey Bed 8060 features a 73 cubic-foot, A-Frame green nylon canopy with four zippered access panels for easy patient access, and ten ports for intravenous lines, call bells and drainage bags. When attached to a compatible commercially available hospital bed (not included), the 8040/8060 is designed to help provide a safe, controlled

environment for patients at extreme risk of injury from a fall or unassisted bed exit.

The Posey Bed 8040 and 8060 hospital bed compatibility guidelines are:

- Length of bed frame must be ≤ 96" and does not retract < 76"
- Width of bed frame must be ≤ 36"
- The height of the bed platform (deck of the bed) from the floormust be able to adjust between:
  - For Posey Bed 8040 –13 and 22 inches
  - For Posey Bed 8060 –16 and 25 inches

Depending on the features of the bed, operational limits must also be observed when a Posey Bed canopy is in use as described in the User Manual. For example, the head of bed angle can only be raised to ≤ 70°.

The Posey Bed 8040/8060 requires that the hospital bed side rails be kept in the "down" position. The canopy contains a specialized compartment for the mattress that helps prevent the mattress from moving within the canopy and the patient from crawling under the mattress. These features provide a system that minimizes the potential for patient entrapment.

Accessories that are specifically for use with the Posey Bed 8040/8060 include travel covers, universal bed straps, , and a pediatric canopy cover and skirt for a more child-friendly appearance. General bed accessories that can be used with the Posey Bed 8040/8060 or any other Posey Bed or hospital bed are filler cushions, a torso cushion, a support surface, an incontinence pad, and headboard/footboard pads,.

INTENDED USE:

The Posey Bed 8040/8060 is an A-Frame bed canopy system. When attached to a compatible hospital bed (not included) the 8040/8060 is

designed to help provide a safe, controlled environment for patients at extreme risk of injury from a fall or unassisted bed exit. The Posey Bed 8040/8060 is a less restrictive alternative to physical restraints such as belts, vests, or jackets for patients at least 46 inches tall, weighing between 46 and 300 pounds. The Posey Bed 8040/8060 is a restraint, and must be prescribed by a licensed physician that includes Rx use in the home environment.

TECHNICAL CHARACTERISTICS: A comparison of device features demonstrates that the Posey Bed 8040/8060 when attached to a compatible hospital bed is substantially equivalent to the currently marketed Posey Bed 8070. The three Posey Bed devices (Models 8040, 8060 and 8070) utilize the same fabrics, mesh, and zippers and are framed, enclosed canopies. The Posey Bed 8040/8060 is also substantially equivalent to the Soma Safe Enclosure which was originally manufactured by Nova Technologies, Inc. (Bristol, Connecticut) and is now manufactured by Vivax Medical Corp (Torrington, Connecticut).

PERFORMANCE TESTING: Results of biocompatibility (ISO 10993), human factors, and performance testing have established that the Posey Bed 8040/8060 is suitable for the intended use indicated and is substantially equivalent to the Posey Bed 8070 and the Soma Safe Enclosure. Human factors testing conducted by caregivers was used to validate the design of a training regimen and Instructions for Use for safe and effective device interactions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Bonnie Bishop, RAC
Vice President, Quality Assurance and Regulatory Affairs
J.T. Posey Company
5635 Peck Road
Arcadia, California 91006

MAY - 2 2012

Re: K113355
Trade/Device Name: Posey Bed 8040 and Posey Bed 8060
Regulation Number: 21 CFR 880.6760
Regulation Name: Protective Restraint
Regulatory Class: I
Product Code: OYS
Dated: April 19, 2012
Received: April 23, 2012

Dear Ms. Bishop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K113355

Device Name: Posey Bed 8040 and Posey Bed 8060

Indications for Use:

The Posey Bed 8040/8060 is an A-Frame canopy system. When attached to a compatible commercially available hospital bed (not included) the 8040/8060 is designed to help provide a safe, controlled environment for patients at extreme risk of injury from a fall or unassisted bed exit. The Posey Bed 8040/8060 is a less restrictive alternative to physical restraints such as belts, vests, or jackets for patients at least 46 inches tall, weighing between 46 and 300 pounds. The Posey Bed 8040/8060 is a restraint, and must be prescribed by a licensed physician that includes Rx use in the home environment.

Prescription Use X AND/OR Over-the-Counter Use ____
(21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

5/1/2012

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices